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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/646,135 | 09/08/2000 | Kazuko Hirabayashi | 44342.011800 | 2368 |

7590 06/11/2003

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[REDACTED] EXAMINER

WHITEMAN, BRIANA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1635 | [REDACTED] |

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------|------------------------|---------------------|
| Advisory Action | Application No. | Applicant(s) |
| | 09/646,135 | HIRABAYASHI ET AL. |
| | Examiner | Art Unit |
| | Brian Whiteman | 1635 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 4 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: ____.

3. Applicant's reply has overcome the following rejection(s): ____.
4. Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 4-11.

Claim(s) withdrawn from consideration: None.

8. The proposed drawing correction filed on ____ is a) approved or b) disapproved by the Examiner.
9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). ____.
10. Other: ____

Continuation of 5. does NOT place the application in condition for allowance because: The 103(a) rejection for claims 4-11 remains for the reasons of record.

The traversal is not found persuasive for the following reasons. Yano and Wooley teach that Poly I:C is known to induce an anti-viral activity in vivo. Canine hepatitis virus and human hepatitis are hepatitis viruses. Other than the assertion that "treatment of canine hepatitis virus by Poly I:C in no way teaches or suggest to the artisan that such treatment would be at all successful in human", the applicants have not provided factual evidence to support their assertion. The specification teaches toxicity studies in a rat with Poly I:C and inducing interferon in the serum of a mouse using Poly I:C. Thus, in view of the totality of the art, one of ordinary skill in the art would have been motivated to use Poly I:C in a human to induce anti-viral activity against a viral (hepatitis) infection.

Furthermore, the traversal that Yano (US Patent 5,298,614) does not teach limiting the size of Poly I:C, the traversal is not found persuasive Yano teaches that Poly I:C in which the molecular size distribution is no more than 4S to 13S induces enough interferon to inhibit effect of tumor in a mouse (columns 23-24). Yano teaches that range of 4S to 13S by a sedimentation constant and 50 to 10,000 by base number. In that case the maximum number of distribution is generally from 100 to 600 base numbers (column 11). Thus, Poly I:C which has a mean chain length within the range of 100 to 500 base pairs is anticipated by Yano.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. dose of Poly I:C administered to mice 100u g/kg in Example 3) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Scott D. Priebe
SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER